



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,368	06/08/2006	Maurice Loretto	1131-16-PCT-PA-TD	6260
22145 7590 12/22/2009 KLEIN, O'NEILL & SINGH, LLP 43 CORPORATE PARK SUITE 204 IRVINE, CA 92606				
EXAMINER				
AHMED, SHEEBA				
ART UNIT		PAPER NUMBER		
1794				
MAIL DATE		DELIVERY MODE		
12/22/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/562,368
Filing Date: June 08, 2006
Appellant(s): LORETTI ET AL.

Brigitte C. Phan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 10, 2009 appealing from the Office action mailed January 27, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

EP 0965443 A1	LORETTI	12-1999
US 5,741,566	HOGSTROM	4-1998
US 5,262,375	MCKEDY	11-1993

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-5, 13, 17, 19, 20, 22, and 23 stand rejected under 35

U.S.C. 102(b) as being anticipated by Loretti (EP 0965443 A1).

Loretti discloses a sterilizable coextruded polymer composite tubular film, the use of such tubular films for the preparation of containers intended for medicaments or infusion solutions. The sterilizable coextruded polymer composite tubular film for use as containers for solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, optionally in a spatially separated arrangement of the contents has a three-layered structure of the tubular film with the following layer sequence : a) polyamide 11 and/or polyetherblock amide b) ethylene/vinyl alcohol copolymer with an ethylene content of 27 to 38 mole %; and c) homophase polypropylene copolymer which is suitable for forming the interior surface of the container. The three-layered structure can be used to prepare tubular films and, therefrom, sterilizable containers,

especially bags, by a multilayer coextrusion blowing method which enable an ecologically compatible disposal. The core of the three-layered structure of the blown film according to the invention is the ethylene/vinyl alcohol copolymer layer with an ethylene content of 27 to 38 mol %. The ethylene/vinyl alcohol copolymer layer b) should have a thickness of 5 to 35 microns. The outer layer a) should have a thickness of 40 to 100 microns and the homophase polypropylene copolymer layer c) which is suitable for forming the interior surface of the said container and thus, being in direct contact with the content, should preferably have a thickness of 60 to 100 microns (See Paragraphs 0001 to 0024). With regard to the limitation that the sterilizable multilayer film has an oxygen transmission rate at 23 °C through the multilayer film determined by the oxygen transmission of the intermediate layer is less than 0.7 ml/m²d and that the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C, the Examiner takes the position that such property limitations are inherent in the multilayer structure taught by Loretti given that the structure of the multilayer film (i.e., the number of layers, etc.) and the chemical composition of each layer within the multilayer film is identical to that of the claimed multilayer film.

2. Claims 6, 18, and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Loretti (EP 0965443 A1) in view of Hogstrom et al. (US 5741566 A).

Loretti, as discussed above, does not teach that the outer layer may be a polyethylene terephthalate layer. However, Hogstrom et al. disclose an autoclavable multi-layer film formed of thermoplastic materials capable of being processed into

hollow shapes and useful for packaging oxygen sensitive materials. The film includes sequential layers A--B--C--D--C--B'--A', wherein the A and A' are layers substantially water and water vapor resistant, wherein at least one of the layers A and A' is made of polyolefins, polyethylene terephthalates, or co-polymers of polyethylene terephthalates (See Abstract). The outermost layers A and A' front the environment and shall be made from a moisture resistant material capable of withstanding both water vapor and liquid water. These layers can be made from the same or different polyolefines or PET (polyethylene-terephthalate) or copolymers of PET (Column 2, lines 55-67).

Accordingly, it would have been obvious to one having ordinary skill in the art to use a polyethylene terephthalate outer layer in the multilayer film taught by Lorette given that Hogstrom et al. teach that the outermost layer fronts the environment and shall be made from a moisture resistant material capable of withstanding both water vapor and liquid water and that such layers can be made from PET (polyethylene-terephthalate) or copolymers of PET.

3. Claims 7-12 and 24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lorette (EP 0965443 A1) in view of McKedy (US 5,262,375 A).

Lorette, as discussed above, does not teach that the laminate or any of the layers within the laminate contain an oxygen absorber such as iron salts.

However, McKedy discloses an oxygen-absorbing composition containing particulate annealed electrolytically reduced iron of between about 100 mesh and 325 mesh in a packet for absorbing oxygen including a stain and grease resistant envelope

containing the oxygen-absorbing composition (See Abstract). Particulate iron is known as an oxygen absorber because it readily combines with oxygen (Column 1, lines 8-10). The oxygen absorber is intended to be used with all types of food products which may be deleteriously affected by the presence of oxygen or any other type of product which is packaged and which must be protected from the deleterious affect of oxygen (Column 4, lines 61-68).

Accordingly, it would have been obvious to one having ordinary skill in the art to add an oxygen absorber to any of the layers of the multilayer film taught by Loretto given that McKedy et al. teach that particulate iron is known as an oxygen absorber because it readily combines with oxygen. Furthermore, it would have been obvious to one having ordinary skill in the art to optimize the amount of the oxygen absorber in the multilayer laminate given that the larger the amount of the oxygen absorber present, the greater the amount of oxygen absorbed by the laminate.

(10) Response to Argument

Appellants traverse the rejection of claims 1-5, 13, 17, 19, 20, 22, and 23 under 35 U.S.C. 102(b) as being anticipated by Loretto (EP 0965443 A1) and the rejection of claims 7-12 and 24 under 35 U.S.C. 103(a) as being unpatentable over Loretto (EP 0965443 A1) in view of McKedy (US 5,262,375 A) and state that even though the '443 Loretto reference discloses a broad genus thickness range of 40 to 100 microns for the outer layer, it specifically teaches "especially from 45 to 75 microns" (col. 3, line 21-23) and in the example given on page 4, paragraph 0027, teaches an outer layer of 50

micron thickness, and as such, as the disclosed broad genus range of 40 to 100 microns taught by Loretta does not cover a species with a range of 20 to 40 microns and that the rejection violates MPEP §2131.03 (II) for failure to disclose a range with "sufficient specificity", which cites the authority of *Atofina v. Great Lakes Chem. Corp.* First, it is the Examiner's position that when the prior art discloses a range which touches or overlaps the claimed range, in order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute" and a case by case determination is made as to anticipation. Furthermore, what constitutes a "sufficient specificity" is fact dependent. In this case, the overlapping range is taught with "sufficient specificity" given that the reference states that the outer layer should have a thickness of 40 to 100 microns. Second, under 35 U.S.C. 102, the entire disclosure of a prior art reference and not just the preferred embodiments can be relied upon to reject the claims. "Applicant must look to the whole reference for what it teaches. Applicant cannot merely rely on the examples and argue that the reference did not teach others." In re Courtright, 377 F.2d 647, 153 USPQ 735,739 (CCPA 1967).

Appellants point to Table 1 in the Appeal Brief, to show that the cited prior art discloses a different material for the outer layer, namely Polyamide 11 or polyetherblock amide (Loretta, Col. 2, lines 29-44) and that Appellants outer layer is made of polyethylene terephthalate and thus the cited reference does not disclose or suggest the characteristics of an outer layer "allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C" and it is the

Appellants position that nowhere in the '443 Lorette reference is disclosed a sterilizable multilayer film having an oxygen transmission rate at 23°C of less than 0.7ml/m²d, having an outer layer having a thickness from 20 to 40 microns, and wherein the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C.

In response to Appellant's argument that the references fail to show certain features of the invention, it is noted that the features upon which Appellants are relying (i.e., **a polyethylene terephthalate outer layer**) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the Examiner has taken the inherency position given that the structure of the **claimed multilayer film** (i.e., the number of layers, etc.) and the chemical composition of the **claimed multilayer film** are identical. Furthermore, once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection has been made, the burden shifts to the Applicants to show the unobvious difference.

Appellants traverse the rejection of claims 6, 18, and 21 under 35 U.S.C. 103(a) as being unpatentable over Lorette (EP 0965443 A1) in view of Hogstrom et al. (US 5741566 A) and submit that Hogstrom discloses superior oxygen impermeability for Films 1 and 5, which have outer layers made of polypropylene and PE/polyamide, respectively, and inferior performance for Film 7, which has an outer layer made of PET and thus it is the Appellants position that Hogstrom clearly does not teach using PET as

an outer layer for a multi-layer film for use in steam sterilization. Appellants further state that it remains necessary to identify some reason for one of ordinary skill in the art to combine an outer layer comprising a PET polymer with an intermediate layer comprising ethylene/vinyl polymer and an inner layer consisting of non-polar polymeric material.

The Examiner disagrees with the Appellants interpretation of Hogstrom. Hogstrom specifically discloses an autoclavable multi-layer film formed of thermoplastic materials capable of being processed into hollow shapes and useful for packaging oxygen sensitive materials. The film includes sequential layers A--B--C--D--C--B'--A', wherein the **A and A' are layers substantially water and water vapor resistant, wherein at least one of the layers A and A' is made of polyolefins, polyethylene terephthalates, or co-polymers of polyethylene terephthalates** (See Abstract). The outermost layers A and A' front the environment and shall be made from a moisture resistant material capable of withstanding both water vapor and liquid water. These layers can be made from the same or different polyolefines or PET (polyethylene-terephthalate) or copolymers of PET (Column 2, lines 55-67). Again, the Examiner would like to point out that the entire disclosure of a prior art reference and not just the preferred embodiments can be relied upon to reject the claims. Furthermore, in response to Appellants' argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. In this case, it would have been obvious to one having ordinary skill in the art to use a polyethylene terephthalate outer layer in the multilayer film taught by Loretti given that Hogstrom et al. teach it is desirable to have an outermost layer that fronts the environment in an autoclavable multi-layer and is made from polyethylene terephthalate which is a moisture resistant material capable of withstanding both water vapor and liquid water.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Sheeba Ahmed/

Primary Examiner, Art Unit 1794

Conferees:

/Callie E. Shosho/

Supervisory Patent Examiner, Art Unit 1794

/Jennifer Michener/

QAS, TC1700